GUIDELINE FOR COMPLETION OF FSIS FORM 9180-16

REFERENCE NO. OF THIS CERTIFICATE 1	**HEALTH CERTIFICATE FOR ANIMAL BY-PRODUCTS FOR THE MANUFACTURE OF TECHNICAL PRODUCTS (Including pharmaceutical products)[1], INTENDED FOR DISPATCH TO THE EUROPEAN COMMUNITY**
EXPORTING COUNTRY **UNITED STATES OF AMERICA**	
RESPONSIBLE MINISTRY U.S. DEPARTMENT OF AGRICULTURE	Note for the importer: This certificate is only for veterinary purposes and has to accompany the consignment until it reaches the border inspection post.
COUNTRY OF DESTINATION 2	CERTIFYING DEPARTMENT FOOD SAFETY AND INSPECTION SERVICE

I. IDENTIFICATION OF ANIMAL BY-PRODUCTS

NATURE OF ANIMAL BY-PRODUCTS AND SPECIES 3	NUMBER OF PARTS OR PACKAGES 4
	NATURE OF PACKAGING 5
NET WEIGHT 6	LOT/BATCH PRODUCTION REFERENCE NUMBER 7

II. ORIGIN OF ANIMAL BY-PRODUCTS

ADDRESS AND VETERINARY CONTROL NUMBER OF THE APPROVED ESTABLISHMENT

8

III. DESTINATION OF ANIMAL BY-PRODUCTS

THE ANIMAL BY-PRODUCT WILL BE SENT FROM (place of loading) 9	TO (country and place of destination) 10
BY THE FOLLOWING MEANS OF TRANSPORTATION 11	NUMBER OF SEAL (if applicable) 12
NAME AND ADDRESS OF CONSIGNOR 13	NAME AND ADDRESS OF CONSIGNEE 14

IV. HEALTH ATTESTATIONS

I, the undersigned official veterinarian, declare that I have read and understood Regulation (EC) No 1774/2002/EC[2] as last amended and certify that the animal by-products described above: 15

A.

1. consists of animal by-products derived from species referred to under Section I above and satisfy the animal health requirements below;

2. have been obtained in the territory of the United States of America :_____16_____[3] from animals:

either[4]

(a) that have remained in this territory since birth or for at least the last three months before slaughter; or

~~(b) killed in the wild in this territory~~[5]. 17

3. have been obtained from animals:

either[4]

(a) coming from holdings:

(i) where, for the following diseases for which the animals are susceptible, there has been neither case/outbreak of rinderpest, swine vesicular disease, Newcastle disease or avian influenza during the prior 30 days, nor of classical or African swine fever during the prior 40 days; nor in the holdings situated in their vicinity within 10 km, during the prior 30 days, and 18

(ii) where there has been neither case/outbreak of foot and mouth disease during the prior 60 days, nor in the holdings situated in their vicinity within 25 km, during the prior 30 days, and

(b) which:

(i) were not killed to eradicate any epizootic disease,

(ii) have remained in their holdings of origin for at least 40 days before departure and which have been transported directly to the slaughterhouse without contact with other animals which did not comply with the same health conditions, and

(iii) at the slaughterhouse, have passed the ante-mortem health inspection during the 24 hours before the slaughter and have shown no evidence of the diseases referred to above for which the animals are susceptible, and

(iv) have been treated in the slaughterhouse before and at the time of slaughter or killing in accordance with the relevant provisions of Council Directive 93/119/EC on animal welfare;19

or

~~(c) captured and killed in the wild in an area:~~

~~(i) in which within 25 km there has been no case/outbreak of any of the following diseases for which the animals are susceptible: foot and mouth disease, rinderpest, classical swine fever, African swine fever, Newcastle disease, avian influenza during the prior 30 days, and~~

~~(ii) that is situated at a distance that exceeds 20 km from the borders separating another territory of a country or part thereof, which is not authorised at these dates for exporting this material to the European Community, and~~

~~(d) which after killing were transported within 12 hours for chilling either to a collection centre and immediately afterwards to a game establishment, or directly to a game establishment.~~ 20

4. have been obtained in an establishment around which, within a radius of 10 km, there has been no case/outbreak of diseases referred to in point (2) for which the animals are susceptible during the prior 30 days or, in the event of a case of disease, the preparation of raw material for exportation to the European Community has been authorised only after removal of all meat, and the total cleaning and disinfection of the establishment under the control of an official veterinarian.

5. have been obtained and prepared without contact with other material not complying with the conditions required above, and it has been handled so as to avoid contamination with pathogenic agents.

6. have been packed in new packaging preventing any leakage and in officially sealed containers bearing the label indicating "RAW MATERIAL ONLY FOR THE MANUFACTURE OF TECHNICAL PRODUCTS INCLUDING PHARMACEUTICAL PRODUCTS" and the name and address of the EU establishment of destination.

7. consists only of[4]:

(a) parts of slaughtered animals, which are fit for human consumption in accordance with Community legislation, but are not intended for human consumption for commercial reasons; 21

(b) parts of slaughtered animals, which are rejected as unfit for human consumption but are not affected by any signs of diseases communicable to humans or animals and derive from carcasses that are fit for human consumption in accordance with Community legislation; 22

~~(c) animal by-products derived from the production of products intended for human consumption, including degreased bones and greaves;~~

~~(d) former foodstuffs of animal origin, or former foodstuffs containing products of animal origin, other than catering waste[5] which are no longer intended for human consumption for commercial reasons or due to problems of manufacturing or packaging defects or other defects which do not present any risk to humans or animals;~~

~~(e) fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production;~~

~~(f) fresh by-products from fish from plants manufacturing fish products for human consumption;~~

~~(g) shells, hatchery by-products and cracked egg by-products originating from animals which did not show clinical signs of any disease communicable through that product to humans or animals;~~

~~(h) fur originating from animals that did not show clinical signs of any disease communicable through product to humans or animals; and~~ 23

8. have been deep-frozen at the plant of origin or have been preserved in accordance with EU legislation in such a way that they will not spoil between dispatch and delivery to the plant of destination.

~~B. Specific requirements~~[4]

~~The by-products in this consignment:~~

~~1.~~[8] ~~Come from animals that have been kept in the territory mentioned under A (2), where vaccination programmes against foot-and-mouth disease are being regularly carried out and officially controlled in domestic bovine animals;~~

~~2.~~[9] ~~consists of offal or de-boned meat.~~ 24

(footnotes pertaining to the above text)

1. Excluding raw blood, raw milk, hides and skins, hooves, and hone, pig bristles and feathers
2. Regulation (EC) No. 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption.
3. The name and ISO code number of the exporting country as laid down in:
   - part 1 of Annex II of Council Decision 79/542/EEC as last amended;
   - the Annex to Commission Decision 94/984/EC as last amended, and;
   - the Annex to Commission Decision 2000/585/EC as last amended.

In addition the ISO code of regionalisation in this Annex (where applicable for the susceptible species concerned) should be included.

4. Delete the appropriate sub-paragraph as .necessary
5. Only for countries from where game meat intended for human consumption of the same animal species is authorised for importation into the European Community
6. Catering waste means all waste food, including used cooking oils, originating in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.
7. Supplementary guarantees to be provided when the material of domestic ruminants originated in the territory of a South American or South African country or part thereof from where only maturated and de-boned fresh meat of domestic ruminants for human consumption is permitted for exportation to the European Community. In the case of offal only trimmed offal of domestic ruminants which must be exclusively offal from which the bones, cartilage, trachea and main bronchi, lymphatic glands adhering connective tissue, fat and mucus have been completely removed is permitted. The whole masseter muscles of bovine animals, incised in accordance with paragraph 41(a) of Chapter VIII of Annex I to Council Directive 64/433/EEC, are also permitted.
8. Only for certain South American countries.
9. Only for certain South American and South African countries.
10. The signature must be in a different colour to that of the printing.

	DONE AT (place) 25	TYPED NAME AND SIGNATURE OF THE OFFICIAL VETERINARIAN[10]
	ON (date) 26	27

RECOMMENDATONS FOR INFORMATION TO BE ENTERED IN EACH NUMBERED BLOCK ON FSIS FORM 9180-16	
Heading Information	
1	Enter the certificate number, MP(F) number, from FSIS Form 9060-5 or the serial number of FSIS Form 9060-9
2	Enter the country of destination within the European Union. Present members of the European Union are: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Ireland, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom. The entry in this block can only be one of these countries.
I. Identification of Animal By-Products	
3	Enter product name and species
4	Enter the number of boxes if shipped in boxes, or if another method of packaging is used such as shipment in 'naked blocks,' enter the number of units to which the shipping container label and the export stamp are applied.
5	Enter the packaging method, e.g., boxes, combo bins, etc.
6	Enter the total net weight of the lot in metric kilograms. Net weight in pounds may be presented with kilogram weight if desired.
7	Enter a number which identifies the lot. If sequential lot or batch numbers are assigned at the plant, they could be used. A range of production dates that appear on the product could be used.
II. Origin of Animal By-products	
8	Enter the establishment number and address of the production plant or the plant number that appears on the shipping container label.
III. Destination of Animal By-products	
9	Enter the city and state where the plant designated on FSIS Form 9060-5 as the "Exported From" plant is located or the city and state of the plant requesting FSIS Form 9060-9.
10	Enter the city within the country of destination and the country of destination to which the product is to be exported.
11	Enter the transportation method. Normally this will be designated as ship, container; ship, break bulk; or air shipment.
12	Enter "Not required" or leave blank.
13	Enter the name and address of the consignor or exporter of the product which should be the same name and address listed in the "Exported By" block of FSIS Form 9060-5 or the Consignor line on the 9060-9.
14	Enter the name and address of the consignee or receiving person or company in the foreign country. Normally this will be the same name and address of the consignee designated on FSIS Form 9060-5 or 9060-9
IV. Health Attestations	
15	The pertinent attestations have been incorporated into this form according to the model certificate. Links to EU Regulation (EC) No 1774/2002/EC and its amendments is provided for the signing official to review if desired.
16	Enter the ISO Code which is "US"
17	Cross out item A. 2. B.
18	FSIS can attest to the absence of animal diseases, if the animals are not susceptible, e.g. poultry diseases usually are not a concern in red meat species, and if there has been no notification of the presence of these diseases through the FSIS Export Library. Avian influenza in this statement refers to 'highly pathogenic avian influenza.'
19	USDA regulations for animal welfare meet the requirements of Council Directive 93/119/EC
20	Cross out A. 3. c. and d.
Select the Appropriate Statement	
21	For product which bears the mark of inspection, retain this statement and cross out A. 7. b.
22	For product which does not bear the mark of inspection (inebible product), retain this statement and cross out A. 7. a.
23	Cross out A. 7. c. – h.
24	Cross out B. 1. – 2. (all of item B.)

Signature, Place of Loading, and Date Blocks	
25	Enter the city and state of the place where the consignment is re-inspected for export (applicant establishment).
26	Enter the date of signature
27	Enter the typed name and signature**, in ink color other than black,** of the FSIS certifying official along with the official's title, e.g., DVM, or VMO. It is recommended that the name of the FSIS VMO be entered only after the name of the official is certain to avoid re-initiation of FSIS Form 9180-16 if the original VMO is unavailable.